**FOOD AND DRUG ADMINISTRATION (FDA)**
Center for Drug Evaluation and Research (CDER)

***Joint Meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)***

FDA White Oak Campus, Building 31, the Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
October 16, 2014

**QUESTIONS**

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1. **DISCUSSION:** Please discuss how you weigh the evidence contributed by the randomized controlled trial (RCT) meta-analyses, observational studies, and spontaneous case reports when evaluating the risk of serious neuropsychiatric adverse events in patients taking varenicline.

2. **VOTE:** Based on the data presented on the risk of serious neuropsychiatric adverse events with varenicline, what would you recommend?

   **A.** Removal of the boxed warning statements regarding risk of serious neuropsychiatric adverse events

   **B.** Modification of the language in the boxed warning

   **C.** Retain the current boxed warning statements and reassess once the ongoing postmarketing randomized controlled trial designed to capture serious neuropsychiatric adverse events is completed

   **DISCUSSION:** Please explain the rationale for your answer, and discuss any additional actions you think the Agency should take regarding the risk of serious neuropsychiatric adverse events with varenicline.